Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0042038	05/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dahl Memorial Healthcare Assn, Inc	106 E Park St, Ekalaka, MT	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of maintenance documentation and interview with testing personnel (TP) #1, the laboratory failed to have a maintenance agreement for their Sysmex-Poch-100i hematology analyzer to ensure calibration and verification was completed from January 1, 2020 to May 25, 2022. Findings: 1. No 2020 and 2021 documentation of preventative maintenance which includes calibration and verification for the Sysmex-Poch-100i hematology analyzer was available for review. 2. Interview with TP #1, on May 25, 2022, at 9:15 AM, confirmed the laboratory failed to have preventative maintenance performed on the Sysmex Poch-100i from January 1, 2020 to May 25, 2022.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)

	-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration records for the Abbott i-STAT Analyzer using CHEM 8+, CG4+, BNP, and cTnl cartridges for analytes sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, total carbon dioxide, pH, PCO2, PO2, B-type Natriuretic Peptide, and cardiac troponin I, and interview with the Testing Personnel (TP) #1, the laboratory failed to perform at least a three-point (a minimal, mid-point, and maximum) calibration verification every six months or after CLEW software updates from January 1, 2020 to May 25, 2022. Findings: 1. Review of calibration records for Abbott i-STAT analyzer lacked documentation of a calibration verification including, at least, a minimal, midpoint, and maximum value for each analyte performed every six months or after CLEW software updates from January 1, 2020 to May 25, 2022. 2. Review of i-STAT: Procedure, Policy # LAB-061 revealed, "8.3.1.2.Calibration Verification (3 levels) will be run after updating if required by manufacturer." 3. Review of Individualized Quality Control Plan Policy #LAB-110 revealed, "VIII. Calibration verification upon CLEW update if required by manufacturer." 4. Review of i-STAT1 System Manual revealed, "Calibration Verification Calibration- Verification procedure is intended to verify the accuracy of results over the entire measurement range of a test as may be required by regulatory or accreditation bodies." 5. Interview with the TP #1 on May 25, 2022, at 11:30 AM, confirmed the laboratory failed to perform at least a three-point calibration verification for analytes performed on the i-STAT analyzer every six months or after CLEW software updates from January 1, 2020 to May 25, 2022.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on record review, procedures, i-STAT System Manual and interview with the Testing Personnel (TP) #1, the laboratory failed to perform monthly external quality controls (QC) on CHEM 8+, CG4+, BNP, and cTnl cartridges as per their laboratory procedure and three levels of external QC for new shipments of cartridges cTnl and BNP as per the manufacturer's instructions from January 1, 2020 to May 25, 2022. Findings: 1. Review of i-STAT: Procedure, Policy # LAB-061 revealed, "10.3 New shipment of cartridges:10.3.4.1 Minimum of 2 levels of liquid QC, or as appropriate" and "10.4.1. All i-STAT testing personnel will participate in performing quality control using liquid controls monthly." 2. Review of i-STAT1 System Manual revealed, "i-STAT cTnI, BNP, AND CK-MB CONTROLS Intended Use i-STAT cTnI, BNP, and CK-MB Control Levels 1, 2, and 3 are intended for use as an assayed quality control material which can be used to verify the integrity of newly received i-STAT cTnI, BNP, and CK-MB cartridges." 3. Review of Individualized Quality Control Plan Policy #LAB-110 revealed, "II. Incoming cartridges b. QC-two levels per lot shipment." 4. A review quality control logs for the i-STAT lacked documentation of monthly external liquid QC checks and three levels of controls for cartridges for cTnl and BNP. 5. Interview with the TP #1 on May 25, 2022, at 11:40 AM, confirmed the laboratory failed to perform monthly QC and three levels of QC for cartridges cTnl and BNP from January 1, 2020 to May 25, 2022.